ORIGINAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent Number: 4,962,098

Patentee: Roger M. Boissonneault

Issue Date: October 9, 1990

Title: Graduated Estrogen Contraceptive

APPLICATION FOR EXTENSION OF PATENT TERM

UNDER 35 U.S.C. §156

Box Patent Ext.
Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Pursuant to §201(a) of the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. §156, WARNER-LAMBERT COMPANY, of 201 Tabor Road, Morris Plains, New Jersey, 07950, the assignee of record, hereby requests an extension of the patent term of United States Patent No. 4,962,098.

The following information is submitted in accordance with 35 U.S.C. §156(d) and 37 C.F.R. §1.740, and follows the numerical format set forth in 37 C.F.R. §1.740.

(1) A complete identification of the approved product as by appropriate chemical and generic name, physical structure or characteristics:

The approved product is Estrostep®. The active

ingredients in Estrostep® are (norethidrone acetate and ethinyl estradiol tablets, USP). Estrostep® is an oral contraceptive. The product consists of tablets having a fixed dosage of norethindrone acetate, and graduated dosages of ethinyl estradiol. Estrostep® 21 are tablets containing 1 mg of norethindrone acetate, and either 20 mcg, 30 mcg, or 35 mcg of ethinyl estradiol. The tablets are administered over a 21-day period. Estrostep® Fe is the same dosage regimen as Estrostep® 21, plus additional tablets of 75 mg of ferrous fumarate administered over an additional 7-day period.

Estrostep® is also known internally within Warner-Lambert Company as "CI-376".

Chemically, the active ingredients in Estrostep® are norethindrone acetate and ethinyl estradiol tablets, USP. These active ingredients have the following structural formulas:

Estrostep® is a pharmaceutical for oral contraceptive use; see the sections titled DESCRIPTION Exhibit 1 (PACKAGE INSERT) which is the Product Information sheet for the approved product.

(2) A complete identification of the Federal statute including the applicable provision of law under which the regulatory review occurred:

The regulatory review occurred under §505(b) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §301 et seq. Section 505 provides for the submission and approval of new drug applications ("NDAs") for products.

(3) An identification of the date on which the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred:

Estrostep® was approved by the Food and Drug Administration ("FDA") for commercial marketing pursuant to §505(b) of the FFDCA on October 9, 1996; see Exhibit 2 (APPROVAL LETTER).

(4) In the case of a human drug product, an identification of each active ingredient in the product and as

to each active ingredient, a statement that it has not been previously approved for commercial marketing or use under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act, or a statement of when the active ingredient was approved for commercial marketing or use (either alone or in combination with other active ingredients), the use for which it was approved, and the provision of law under which it was approved.

The active ingredients in Estrostep® are norethindrone acetate and ethinyl estradiol. Each of these individual agents have been approved previously. See Ethinyl Estradiol USP, USAN, 1996, page 276, and Norethindrone acetate USP, USAN, 1996, page 496. These agents have been approved in fixed dosage combinations for use as oral contraceptives. Such fixed combinations have been approved under § 505 of FFDCA, e.g. product numbers N17875 and N17876. Estrostep® is a fixed dosage of norethindrone acetate and a graduated dosage regime of ethinyl estradiol. The dosage combination of Estrostep® has not been previously approved.

(5) A statement that the application is being submitted within the sixty day period permitted for submission pursuant to §1.720(f) and an identification of the date of the last day on which the application could be submitted.

The product was approved for commercial marketing on October 9, 1996, and the last day within the sixty day period

permitted for submission of an application for extension of the patent is December 7, 1996. The date of submission of the present application is no later than December 7, 1996, and therefore, the present application has been timely filed.

(6) A complete identification of the patent for which an extension is being sought by the name of the inventor, the patent number, the date of issue, and the date of expiration:

U.S. PATENT NUMBER:	4,962,098
INVENTOR:	Roger M. Boissonneault
Issue Date:	October 9, 1990
Expiration Date:	October 9, 2007

(7) A copy of the patent for which an extension is being sought including the entire specification (including claims) and drawings:

A copy of U.S. Patent 4,962,098 is attached as Exhibit 3 (PATENT).

(8) A copy of any disclaimer, certificate of correction, receipt of maintenance fee payment, or reexamination certificate issued in the patent:

No disclaimer, certificate of correction or reexamination certificate has been issued. A copy of the receipt showing the first maintenance fee being paid is attached as Exhibit 4.

(9) A statement that the patent claims the approved product or a method of using or manufacturing the approved product, and a showing which lists each applicable patent claim and demonstrates the manner in which each applicable patent claim reads on the approved product or a method of using or manufacturing the approved product:

The patent claims the method of using the approved product Estrostep® in claims 1-9.

Claims 1-9 are set forth below:

Claim 1.

1. A method of contraception comprising the steps of sequentially-administering to a female of child bearing age:

(1) for about 4 to about 7 days, a composition I containing about 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol,

(2) for about 5 to about 8 days, a composition II containing about 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol, and

(3) for about 7 to about 12 days, a composition III containing 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl

estradiol, wherein the amount of ethinyl estradiol is increased stepwise by the amount of at least 5 mcg in each step.

Claim 2.

The method of claim 1 which comprises the additional step of administering, for about 7 days, a composition IV containing ferrous fumarate.

Claim 3.

The method of claim 1 wherein composition I contains about 0.5-1.5 mg norethindrone acetate and about 10-30 mcg ethinyl estradiol; composition II contains 0.5-1.5 mg norethindrone acetate and 20-40 mcg ethinyl estradiol; and composition III contains 0.5-1.5 mg norethindrone acetate and about 30-50 mcg ethinyl estradiol.

Claim 4.

The method of claim 1 wherein composition I is administered for about 5 days and contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol; composition II is administered for about 7 days and contains about 1.0 mg norethindrone acetate and about 30 mcg ethinyl estradiol; and composition III is administered for about 9 days and

contains about 1.0 mg norethindrone acetate and about 40 mcg ethinyl estradiol.

Claim 5.

The method of claim 4 wherein the compositions are administered in combination with a suitable carrier.

Claim 6.

The method of claim 1 wherein composition I is administered for about 5 days and contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol; composition II is administered for about 7 days and contains about 1.5 mg norethindrone acetate and about 30 mcg ethinyl estradiol; and composition III is administered for about 9 days and contains about 1.0 mg norethindrone acetate and about 50 mcg ethinyl estradiol.

Claim 7.

The method of claim 6 wherein the compositions are administered in combination with a suitable carrier.

Claim 8.

The method of claim 1 wherein composition I is administered for about 5 days and contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl

estradiol; composition II is administered for about 7 days and contains about 1.0 mg norethindrone acetate and about 30 mcg ethinyl estradiol; and composition III is administered for about 9 days and contains about 1.0 mg norethindrone acetate and about 35 mcg ethinyl estradiol.

Claim 9.

The method of claim 8 wherein the compositions are administered in combination with a suitable carrier.

Regarding Claim 1

Claim 1 requires "A method of contraception..." Estrostep® is an oral contraceptive.

Claim 1 requires "...the steps of sequentially-administering..." Estrostep® 21 is comprised of 21 tablets, each containing 1 mg norethindrone acetate, (NA) and varying quantities of ethinyl estradiol (EE) of 20 mcg (composition I), 30 mcg (composition II) and 35 mcg (composition III). The tablets are administered sequentially.

Claim 1 requires administering "...for about 4 to about 7 days, a composition I containing about 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol...." Five tablets of Estrostep® 21 contain 1 mg NA and 20 mcg EE. These are given one each day for days 1-5 (5 days) of the 21 day dosing cycle.

Claim 1 requires administering "...for about 5 to about 8 days, a composition II containing about 0.5 - 1.5 mg norethindrone acetate and about 10 - 50 mcg ethinyl estradiol...." Seven tablets of Estrostep® 21 contain 1 mg NA and 30 mcg EE. These are administered one each day during days 6-12 (7 days) of the 21 day cycle.

Claim 1 requires administering "...for about 7 to about 12 days, a composition III containing 0.5-1.5 mg norethindrone acetate and about 10-50 mcg ethinyl estradiol...." Nine tablets of Estrostep® 21 contain 1 mg NA and 35 mcg EE. These are administered one each day for days 13-21 (9 days) of the 21 day cycle.

Claim 1 requires "...wherein the amount of ethinyl estradiol is increased stepwise by the amount of at least 5 mcg in each step." Estrostep® 21 has five tablets containing 20 mcg EE, seven tablets containing 30 mcg EE, and nine tablets containing 35 mcg EE.

Regarding Claim 2

Claim 2 requires "The method of claim 1 which comprises the additional step of administering for about 7 days, a composition IV containing ferrous fumarate." Estrostep® Fe is the same dosage regimen as Estrostep® 21 recited above, plus an additional seven tablets each containing 75 mg ferrous fumarate. These are administered one tablet per day for 7

days following completion of the Estrostep® 21 regimen (i.e., days 22-28).

Regarding Claim 3

Claim 3 requires the contraceptive method of claim 1 wherein "...composition I contains about 0.5-1.5 mg norethindrone acetate and about 10-30 mcg ethinyl estradiol...." Estrostep® 21 is comprised of 21 tablets to be administered sequentially for contraception. The dosing regimens are listed below as I, II and III.

I. Five tablets of Estrostep® 21 contain 1 mg NA and 20 mcg EE. These amounts fall within the requirements of Claim 3.

II. Seven tablets of Estrostep® 21 contain 1 mg NA and 30 mcg EE. Claim 3 requires "...Composition II contains 0.5-1.5 mg norethindrone acetate and 20-40 mcg ethinyl estradiol...."

III. Nine tablets of Estrostep® 21 contain 1 mg NA and 35 mcg EE. Claim 3 requires "...and composition III contains 0.5-1.5 mg norethindrone acetate and about 30-50 mcg ethinyl estradiol...."

Regarding Claim 4

Claim 4 requires the contraceptive method of claim 1 wherein "...composition I is administered for about 5 days and contains about 1.0 mg norethindrone acetate and about 20 mcg

ethinyl estradiol...." Tablets of Estrostep® 21 for contraception to be administered in days 1-5 (composition I) of the 21 day cycle contain 1 mg NA and 20 mcg EE.

Composition II of Estrostep® 21 is 7 tablets each containing 1 mg NA and 30 mcg EE. They are to be administered one each day for 7 days. Claim 4 requires "...composition II is administered for about 7 days and contains about 1.0 mg norethindrone acetate and about 30 mcg ethinyl estradiol...."

Composition III of Estrostep® 21 is 9 tablets each containing 1 mg NA and 35 mcg EE. They are administered one each day for 9 days. Claim 4 requires "...composition III is administered for about 9 days and contains about 1.0 mg norethindrone acetate and about 40 mcg ethinyl estradiol." In this case, 35 mcg EE in Estrostep® is "about 40 mcg ethinyl estradiol" required by claim 4.

Regarding Claim 5

Each tablet of Estrostep® 21, in addition to NA and EE, contains calcium stearate, lactose, microcrystalline cellulose and starch. (See Description in Exhibit 1). These are standard pharmaceutical carriers. Claim 5 requires "...wherein the compositions are administered in combination with a suitable carrier."

Regarding Claim 6

Claim 6 requires the method of contraception of claim 1 wherein "... composition I is administered for about 5 days

and contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol...." Composition I of Estrostep® 21 is administered for 5 days, with each tablet containing 1 mg NA and 20 mcg EE.

Claim 6 requires "...composition II is administered for about 7 days and contains about 1.5 mg norethindrone acetate and about 30 mcg ethinyl estradiol...." Composition II of Estrostep® 21 is administered for 7 days and contains 1 mg NA and 30 mcg EE. The 1 mg NA of Estrostep® is "about 1.5 mg norethindrone acetate" required by claim 6.

Claim 6 requires "and composition III is administered for about 9 days and contains about 1.0 mg norethindrone acetate and about 50 mcg ethinyl estradiol." Composition III of Estrostep® 21 is administered for 9 days, each tablet containing 1.0 mg NA and 35 mcg EE. The 35 mcg EE in Estrostep® is "about 50 mcg ethinyl estradiol" required by claim 6.

Regarding Claim 7

Claim 7 requires "The method of claim 6 wherein the compositions are administered in combination with a suitable carrier." The compositions of Estrostep® 21 contain, in addition to NA and EE, calcium stearate, lactose, microcrystalline cellulose and starch. These are "suitable carriers" as required by claim 7.

Regarding Claim 8

Claim 8 requires the contraceptive method of claim 1 wherein: "...composition I is administered for about 5 days and contains about 1.0 mg norethindrone acetate and about 20 mcg ethinyl estradiol...." Composition I of Estrostep® 21 is administered one tablet each day for 5 days, each tablet containing 1.0 mg NA and 20 mg EE.

Claim 8 requires "...composition II is administered for about 7 days and contains about 1.0 mg norethindrone acetate and about 30 mcg ethinyl estradiol...." Composition II of Estrostep® 21 is administered for 7 days and each tablet contains 1.0 mg NA and 30 mcg EE.

Claim 8 requires "...composition III is administered for about 9 days and contains about 1.0 mg norethindrone acetate and about 35 mcg ethinyl estradiol." Composition III of Estrostep® 21 is administered for 9 days and each tablet contains 1.0 mg NA and 35 mcg EE.

Regarding Claim 9

Claim 9 requires the method of claim 8 "...wherein the compositions are administered in combination with a suitable carrier." The compositions of Estrostep® 21 contain, in addition to NA and EE, calcium stearate, lactose, microcrystalline cellulose and starch. These are "suitable carriers" as required by claim 9.

(10) A statement beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. §156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows:

(i) For a patent claiming a human drug, antibiotic, or human biological product, the effective date of the investigational new drug (IND) application and the IND number; the date on which a new drug application (NDA) or a Product License Application (PLA) was initially submitted and the NDA or PLA number and the date on which the NDA was approved or the Product License issued;

On July 18, 1988, Warner-Lambert Company submitted to the Food and Drug Administration a "Notice of Claimed Investigational Exemption for a New Drug" (IND) for norethindrone acetate and ethinyl estradiol tablets, USP (Estrostep®, CI-376). A copy of this letter is submitted herewith as Exhibit 5 (IND SUBMISSION LETTER).

The IND was assigned number 31,861. It was received by the FDA on July 20, 1988. The IND became effective on August

19, 1988, which is thirty days after receipt of the IND by the FDA; see Exhibit 6 (IND ACKNOWLEDGMENT LETTER) attached hereto. This establishes the beginning of the "regulatory review period" under 35 U.S.C. §156(g)(1) as August 19, 1988.

On December 27, 1990, a new drug application (NDA 20-130) was submitted under §505(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and §314.50 of Title 21 Code of Federal Regulations for Estrostep® by the Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company. A copy of the cover letter attached to the NDA of December 27, 1990, is submitted herewith as Exhibit 7 (NDA SUBMISSION LETTER).

By letter dated August 27, 1992, the FDA indicated that NDA 20-130 was nonapprovable for various manufacturing reasons not associated with safety or efficacy. Warner-Lambert responded on September 3, 1992, that the NDA would be amended. Copies of these letters are Exhibit 8. Warner-Lambert diligently worked with the FDA to modify and correct manufacturing operations so as to comply with FDA requirements.

The NDA was amended on April 9, 1996. A copy of the cover letter attached to the amendment is attached as Exhibit 9 (AMENDMENT TO A PENDING APPLICATION).

The amended NDA was approved on October 9, 1996. Attached as Exhibit 2 (APPROVAL LETTER) is a copy of a letter

dated October 9, 1996, from the FDA to Warner-Lambert Company approving the NDA for Estrostep® 21 (norethindrone acetate and ethinyl estradiol) Tablets and Estrostep® Fe (norethindrone acetate and ethinyl estradiol tablets and ferrous fumarate) Tablets.

Thus, for the purposes of determining the "regulatory review period" under 35 U.S.C. §156(g)(1), the date of the first approval of Estrostep® is October 9, 1996.

(11) A brief description, beginning on a new page, of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities:

As described above in item (10), the IND for Estrostep® became effective on August 19, 1988. The clinical studies under the IND are summarized in the attached Exhibit 10 (IND LOG). These clinical studies were used to support NDA 20-130 submitted by Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company on December 27, 1990.

Subsequent to the submission of the NDA, WARNER-LAMBERT COMPANY had numerous contacts and meetings with the FDA with respect to the application and these are summarized in the attached Exhibit 11,(NDA LOG).

(12) A statement, beginning on a new page, that in the opinion of the applicant the patent is eligible for the extension and a statement as to the length of the extension claimed, including how the length of extension was determined:

Statement of Eligibility of the Patent for Extension Under 35 U.S.C. §156(a) and (c)(4)

Section 156(a) provides, in relevant part, that the term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended if (1) the term of the patent has not expired before an application for extension is submitted, (2) the term of the patent has never been extended, (3) the application for extension is submitted by the owner of record of the patent or its agent in accordance with 35 U.S.C. §156(d), (4) the product has been subject to a regulatory review period before its commercial marketing or use, and (5) the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; and §156(c)(4) provides, that in no event shall more than one patent be extended for the same regulatory review period for any product.

As described by corresponding number, each of these elements is satisfied here:

(1) The statutory term of U.S. Patent No. 4,962,098 expires on October 9, 2007. This Application has, therefore, been submitted before the expiration of the patent term. All required maintenance fees have been paid.

(2) The term of this patent has never been extended.

(3) This Application is submitted by Warner-Lambert Company, the owner of record of Patent 4,962,098, by assignment recorded at Reel 5071, frame 0048. This application is submitted in accordance with 35 U.S.C. §156(d) in that it is submitted within the sixty-day period beginning on the date, October 9, 1996, that the product received permission for marketing under the Federal Food, Drug and Cosmetic Act and contains the information required under 35 U.S.C. §156(d).

(4) As evidenced by the October 9, 1996, letter from the FDA, Exhibit 2, (APPROVAL LETTER) the product was subject to a regulatory review period under §505(b) of the FFDCA before its commercial marketing or use.

(5) The permission for the commercial marketing of Estrostep® after regulatory review under §505(b) is the first permitted commercial marketing of the approved product. This is confirmed by the absence of any approved new drug application under which Estrostep® could be commercially marketed prior to October 9, 1996.

Statement as to Length of Extension Claimed

In Accordance With 37 C.F.R. §1.775

The term of U.S. Patent No. 4,962,098 should be extended for a period of 1096 days to October 9, 2010.

The period of extension is determined in accordance with 35 U.S.C. §156 and follows the format set forth in 37 CFR §1.775(c) and (d).

37 CFR §1.775(c) The length of the regulatory review period for a human drug, antibiotic drug or human biological product will be determined by the Secretary of Health and Human Services. Under 35 U.S.C. §156(g)(1)(B), it is the sum of --

(1) The number of days in the period beginning on the date an exemption under subsection (i) of section 505 or subsection (d) of section 507 of the Federal Food, Drug, and Cosmetic Act became effective for the approved product and ending on the date the application was initially submitted for such product under those sections or under section 351 of the public Health Service Act;

The number of days between the effective date of the IND, August 19, 1988, and the initial submission of the NDA, December 27, 1990, is a

period of 861 days

and

(2) The number of days in the period beginning on the date the application was initially submitted for the approved product under section 351 of the Public Health Service Act, subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act and ending on the date such application was approved under such section.

The number of days between the initial submission of the NDA, December 27, 1990, to NDA approval, October 9, 1996, is a period of 2114 days.

37 C.F.R. §1.775(d) The term of the patent as extended for a human drug, antibiotic drug or human biological product will be determined by--

(1) Subtracting from the number of days determined by the Secretary of Health and Human Services to be in the regulatory review period:

(i) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section which were on and before the date on which the patent issued;

The number of days in the period of the IND,

effective on August 19, 1988, which were on or before October 9, 1990, the date the patent was issued, is a period of 782 days,

861 days minus 782 days equals 79 days,
and
the number of days in the period of the NDA, initial submission of December 27, 1990, which were on or before October 9, 1990, the date the patent was issued, is a period of 0 days,

2114 days minus 0 days equals 2114 days.

(ii) The number of days in the periods of paragraphs (c)(1) and (c)(2) of this section during which it is determined under 35 U.S.C. §156(d)(2)(B) by the Secretary of Health and Human Services that applicant did not act with due diligence;

The number of days the applicant did not act with due diligence is 0 days,

therefore,
861 days minus 0 days equals 861 days.
2114 days minus 0 days equals 2114 days.

(iii) One-half the number of days remaining in the period defined by paragraph (c)(1) of this section after that period is reduced in accordance with paragraphs (d)(1)(i) and (ii) of this section; half days will be ignored for purposes of subtraction;

One-half of 79 days equals 39 days.

Thus U.S. Patent No. 4,962,098 should be entitled to an extension of 2153 days (39 days plus 2114 days).

(2) By adding the number of days determined in paragraph (d)(1) of this section to the original term of the patent as shortened by any terminal disclaimer;

Adding 2153 days to October 9, 2007, the original term of the patent (no terminal disclaimer was made), extends the term to August 31, 2013.

(3) By adding 14 years to the date of approval of the application under section 351 of the Public Health Service Act, or subsection (b) of section 505 or section 507 of the Federal Food, Drug, and Cosmetic Act;

Adding 14 years to October 9, 1996, the date of approval of the application, gives the date of October 9, 2010.

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

The earlier date is October 9, 2010.

(5) If the original patent was issued after September 24, 1984,

(i) By adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer;

Adding 5 years to the original expiration date of the patent (October 9, 2007) gives the date of October 9, 2012.

and

(ii) By comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date:
Comparing October 9, 2010, and October 9, 2012, the earlier date is October 9, 2010, and the patent term should therefore be extended to October 9, 2010.

(6) If the original patent was issued before September 24, 1984,

This is not applicable for the patent.

(13) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and to the Secretary of Health and Human Services any information which is material to any determination to be made relative to the application for extension.

Applicant is unaware of any additional information material to this Application for extension.

(14) Prescribed Fee:

The prescribed fee of $1,090.00 for receiving and acting on this application for extension of patent term is hereby authorized. Please charge Deposit Account No. 23-0455 in the amount of the fee above, or such greater or lesser amount as the Commissioner determines is required by law.

(15) The name, address and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed:

Charles W. Ashbrook
Registration No. 27,610
Assistant General Counsel,
Pharmaceutical Patents
WARNER-LAMBERT COMPANY
Pharmaceutical Research Division
2800 Plymouth Road
Ann Arbor, Michigan 48105
Tel: (313) 996-5215
Fax: (313) 996-1553

(16) A duplicate of the application papers, certified as such.

A duplicate of the application papers, certified as such, is submitted herewith.

(17) An oath or Declaration as set forth in paragraph (b) of 37 C.F.R. §1.740.

DECLARATION

The undersigned is authorized on behalf of WARNER-LAMBERT COMPANY, the owner of record of U.S. Patent 4,962,098, to apply for an extension of the term of this patent. I declare that: I have reviewed and understand the contents of this Application being submitted pursuant to 35 U.S.C. § 156; that I believe that the patent is subject to extension pursuant to 37 C.F.R. § 1.710; that I believe that the length of extension claimed is fully justified under 35 U.S.C. §156 and the applicable regulations; and that I believe that the patent for which this extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 C.F.R. § 1.720.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application and any extension of U.S. Patent No. 4,962,098.

WARNER-LAMBERT COMPANY

Date: November 20, 1996

By: Charles W. Ashbrook

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